IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

IN RE: RECALLED ABBOTT INFANT FORMULA PRODUCTS LIABILITY LITIGATION	)	**Case No. 1:22-cv-04148**
	)	**MDL No. 3037**
This Document Relates to All Cases	)	**Hon. Judge Matthew F. Kennelly**

PLAINTIFFS' BRIEF REGARDING ABBOTT'S DISCOVERY RESPONSES

Following the August 11, 2023 status conference, Plaintiffs submit this brief regarding Abbott's discovery responses, as follows:

INTRODUCTION

The issue before this Court is whether to allow Abbott to determine relevance and proportionality on its own, decline to produce relevant documents, and drive up the costs of this case. Indeed, Abbott has:

> (1) Proposed a January 1, 2020 date range for document production, even though contamination existed at Abbott's Sturgis facility well before then;
>
> (2) Refused to produce documents regarding related injuries to children that could have been caused by its Sturgis-produced, powdered infant formula ("PIF") products, even though Abbott previously and voluntarily produced these very documents in the Preterm Infant Nutrition MDL; and
>
> (3) Declined to produce documents regarding safety practices at its Casa Grande facility, even though Abbott manufactured PIF at and presumably instituted safety procedures and standards for that facility that may or may not fall in line with those it failed to put in place at Sturgis.

The date range Plaintiffs propose, and the documents Plaintiffs seek, are relevant and proportional to the needs of this case, which concerns systemic failures in contamination controls for a product marketed to a vulnerable subgroup that often relies on it as a sole source of food. Rather than follow Abbott's constricted interpretation of the Federal Rules of Civil Procedure, this

Court should order Abbott to produce relevant documents that are squarely proportional to the needs of this case and allow Plaintiffs to prepare their cases for trial.

The parties have followed Local Rule 37.2 and this Court's procedures concerning discovery disputes and discussed these issues several times.[1] Despite the parties' productive efforts, these disputes remain unresolved, and Court intervention is now necessary. This Court, in turn, should reject Abbott's stingy, one-sided view of discovery.[2]

ARGUMENTS

1. Plaintiffs' Date Range Is Reasonable.

a. Plaintiffs' Date Range Is Narrowly Tailored.

The primary substantive dispute is the presumptively applicable date range in Plaintiffs' discovery requests. Plaintiffs define the relevant time period as January 1, 2018 to present. Abbott, however, insists on a January 1, 2020 cut-off date in defiance not only of discoverability standards, but also its public record of relevant conduct involving the same factory and microbes at issue.[3]

This case centers on Abbott's delivery of contaminated PIF into the steam of commerce that led to infections, hospitalizations, and infant deaths. These illnesses were caused by Abbott's failure to ensure that sufficient contamination controls were in place during the manufacturing process of a product that often serves as the sole food source for a vulnerable population. Naturally, documents regarding conditions at Abbott's facilities where infant formulas were manufactured

[1] *See* Joint Status Report for August 11, 2023 Case Management Conference (Dkt. 169) at p. 3 (detailing the parties' discussions).
[2] *Cf. Rossetto v. Pabst Brewing Co*., 217 F.3d 539, 542 (7th Cir. 2000) (acknowledging "the district court's welcome effort to expediate the litigation and spare the parties the expense of protracted discovery, the bane of modern litigation").
[3] Alternatively, Abbott claims that it will agree "to a compromise position that would include additional select categories of documents pre-dating 2020." Status Report (Dkt. 169) at p. 9. But this proposal suffers from the same infirmity—Abbott's insistence on piecemeal discovery.

will show whether, and to what extent, Abbott failed to abide by industry practices for safe manufacturing. These documents will also show the extent and duration of contamination. Unfortunately for Abbott, its safety record is far from stellar.

More than a decade ago, the FDA criticized Abbott for failing to "manufacture foods under conditions and controls necessary to minimize contamination."[4] The situation worsened. In 2018, the FDA inspected Abbott's Sturgis facility.[5] Abbott, in turn, submitted reports for two instances of confirmed *Cronobacter* results.[6] Abbott also received at least two complaints involving *Cronobacter* infections in infants—the very same deadly microbe cited by the FDA and Abbott at the time of the recall and that resulted in the closure of its Sturgis plant.[7]

The next year, the FDA blasted Abbott for inadequate testing of PIF at the Sturgis facility.[8] Indeed, the FDA found that Abbott had taken insufficient steps to ensure that these products met "required microbiological quality standards."[9] By this time, a former Abbott employee who worked at the Sturgis facility came forward to report the conditions at the Sturgis facility. Through his attorney, the Complainant submitted a 34-page report in which he accused Abbott of, among other things, falsifying records, withholding information regarding food safety, and releasing untested infant formulas.[10] Specifically, this Complaint details allegations of systemic issues back

[4] *See* FDA, Form 483 (Oct. 22, 2010), *available at* https://www.fda.gov/media/79030/download (last visited Aug. 22, 2023).
[5] FDA Sept. 28, 2018 Establishment Inspection Report, *available at* https://www.fda.gov/media/159323/download (last visited Aug. 22, 2023).
[6] *Id*.
[7] *Id*.
[8] FDA Form 483 (Sept. 24, 2019), *available at* https://www.fda.gov/media/157319/download (last visited Aug. 22, 2023). This document, on its own, shows that problems existed before Abbott's proposed date range.
[9] *Id*.
[10] *See* https://int.nyt.com/data/documenttools/confidential-disclosure-re-abbott-laboratories-10-19-2021-redacted-1/b9ec16287b0384d3/full.pdf (last visited Aug. 22, 2023).

to and including the FDA's audit of the facility to at least 2019. Ultimately, on May 16, 2022, Abbott entered a Consent Decree of Permanent Injunction with the U.S. Government that described its violations of numerous statutes based on its having brought to market adulterated infant formula.[11] The Consent Decree also contains a requirement of an expert investigation for *Cronobacter* positive results dating back to 2019.

The publicly available evidence already uncovered shows that Abbott repeatedly failed to maintain controls necessary to avoid contamination back to at least 2018. Discovery will shed more light on these allegations. Adopting Abbott's truncated date range, however, will allow Abbott to withhold evidence that is relevant to Plaintiffs' claims.

Abbott's incomplete date range contradicts the history of its manufacturing practices and documented contamination of its products. Further, the truncated time period prejudices Plaintiffs with injuries that pre-date 2020. As one example, the San Miguel family sued Abbott and alleged that Abbott's infant formula caused a child to be hospitalized for a *Cronobacter Sakazakii* meningitis infection that was so extensive that it necessitated removal of nearly half the child's brain.[12] The *San Miguel* case involves nearly the same claims as every other plaintiff and concerns the same allegations made about safety conditions at the Sturgis facility. Notably, the injured child

[11] Consent Decree of Permanent Injunction, ECF. No. 8, 1:22-cv-00551 (W.D. Mich. May 16, 2022), *available at* https://dam.abbott.com/en-us/documents/pdfs/transparency/ECF-008-Consent-Decree.pdf (last visited Aug. 22, 2023). This document was signed by Lori Randall, Abbott's Division Vice President for Quality Assurance, Keenan Gale, Sturgis Quality Operations Director, and TJ Hathaway, Sturgis Site Operations Director.

[12] Plaintiff's Original Complaint (Dkt. 1) at p. 5, ¶ 14, *San Miguel v. Abbott Laboratories d/b/a Abbott Nutrition et al.*, Case 1:23-cv-02515; In the United States District Court for the Northern District of Illinois, Eastern Division. *San Miguel* was filed in federal court in Illinois and transferred into this MDL without any objection by Abbott. Abbott cannot have it both ways – either the case is properly within the MDL and the discovery available to Plaintiffs must be allowed for the corresponding time period to the injuries, or the case should not be within the MDL if Abbott is not required to produce the relevant discovery for the case. Abbott made its choice to allow the Complaint to proceed in the MDL and should thus produce the discovery.

consumed contaminated infant formula "[i]n or around August through September of 2019."[13] Adopting Abbott's arbitrary date range would deprive the San Miguel family of documents from the year before and the year of their injured child's hospitalization. But even without the *San Miguel* case, and as shown above, evidence of Abbott's safety violations and haphazard safety practices is more than ample.

Another observation about e-discovery is warranted. The parties here agreed to a list of search terms to be used to locate documents in discrete areas responsive to Plaintiffs' discovery requests. Using these agreed search terms naturally limits the number of documents that are produced. Assuming, as Abbott contends, that there were no conditions at its facilities that led to contamination, the search terms would not result in any responsive documents.

Conversely, despite its arguments about the burden associated with the scope of Plaintiffs date range, Abbott expressly acknowledges that there are responsive documents that predate January 1, 2020. In the Status Report, Abbott advised that it has "already produced, and is willing to agree to a compromise position that would include *additional select categories of documents pre-dating 2020*."[14] The PSC's date range will not result in the cost of collecting additional documents given that Abbott's counsel's representation that they already started collecting custodial documents going back to January 1, 2018. This concession further shows that a January 1, 2018 date range is reasonable and should be adopted.

b. Plaintiffs' Date Range Will Plainly Lead To The Production of Relevant Documents.

"[D]iscovery allows relevant evidence, not just strongly convincing evidence since the parties cannot know at this stage what evidence will make a difference in the case's final outcome."

[13] *Id*. at p. 25, ¶ 22.
[14] *See* Joint Status Report for August 11, 2023 Case Management Conference (Dkt. 169) at p. 9 (emphasis added).

Arrow Enter. Computing Sols., Inc. v. BlueAlly, LLC, 2017 WL 876266, at *6 (E.D.N.C. Mar. 3, 2017). Parties "may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense . . . ." FED. R. CIV. P. 26(b)(1). Evidence is relevant if "it has any tendency to make a fact more or less probable than it would be without the evidence" and "the fact is of consequence in determining the action." FED. R. EVID. 401(a)-(b).[15] This is not a daunting standard, and as shown above, Plaintiffs have met it.

Abbott instead generally and globally asserts that many of the documents that Plaintiffs seek will not ultimately help Plaintiffs' case.[16] But relevance, not admissibility, is the issue now before this Court. Relevance and admissibility are separate issues with different standards.[17] Abbott, however, conflates both concepts in its briefing.

Plaintiffs' date range is based on a comprehensive review of publicly available information, which has shown safety issues at Abbott's facility and safety concerns about Abbott's products. Abbott may well wish to file motions *in limine* if it wants to contend that Rule 403 precludes any mention of responsive documents at trial.[18] For now, Plaintiffs should receive these documents to develop their cases.

c. Plaintiffs' Date Range Is Proportional To The Needs Of This Case.

Parties may obtain discovery regarding any nonprivileged matter that is "proportional to the needs of the case." FED. R. CIV. P. 26(b)(1). Both sides have burdens in arguing proportionality. *Deal Genius, LLC v. O2Cool, LLC*, 2023 WL 4556759, at *4 (N.D. Ill. July 14, 2023). Those

[15] Indeed, whether a document is relevant does not depend on whether it will ultimately help or hurt one side or another. *See id*.
[16] *See, e.g.*, Joint Status Report for August 11, 2023 Case Management Conference (Dkt. 169) at pp. 11-12.
[17] *See* FED. R. EVID. 401; FED. R. EVID. 402; FED. R. EVID. 403; *see also Tate v. DG La. LLC*, --- F. Supp. ---, 2023 WL 1438325, at *3 (E.D. La. Feb. 1, 2023) ("The threshold for relevance at the discovery stage is lower than the threshold for relevance of admissibility of evidence at the trial stage." (footnote omitted)).
[18] Plaintiffs reserve the right to respond to any such motions.

seeking discovery must "identify the benefits of the sought-after discovery and why they ultimately need it." *Id*. (footnote omitted). Those opposing discovery "must in turn supply hard information substantiating claimed burdens." *Id*. (footnote omitted).

Proportionality is a case-specific determination. *E.g.*, *Hahn v. Ohio Sec. Ins. Co.*, 2023 WL 2138926, at *2 (N.D. Okla. Feb. 21, 2023); *cf. In re Rail Freight Fuel Surcharge Antitrust Litig (No. II)*, 2021 WL 1909777, at *18 (D.D.C. May 12, 2021) ("evaluation of any discovery dispute under Rule 26 is highly context-specific"). This concept "requires a common sense and experiential assessment." *Generation Brands, LLC v. Décor Selections, LLC*, 2020 WL 6118558, at *4 (N.D. Ill. Oct. 16, 2020) (citation omitted). Courts apply six factors:

> (1) The importance of the issues at stake in the action;
> (2) The amount in controversy;
> (3) The parties' relative access to relative information;
> (4) The parties' resources;
> (5) The importance of the discovery in resolving the issues; and
> (6) Whether the burden or expense of the proposed discovery outweighs its likely benefit.

FED. R. CIV. P. 26(b)(1). Although none of these factors should "necessarily predominate," the last two factors are normally the most important ones. *O2Cool, LLC*, 2023 WL 4556759, at *4. Here, each Rule 26 factor supports Plaintiffs' proportionality arguments.[19]

Importance of the Issues. Because this case involves the most important pediatric food safety concerns in recent memory, drawing the attention and action of the legislative and executive branches, there are particularly important issues that will be resolved. And because this case is "a

[19] According to Abbott, "Plaintiffs do not point to *any compelling need* to extend searches back to 2018." *See* Joint Status Report for August 11, 2023 Case Management Conference (Dkt. 169) at p. 9 (emphasis added). Rule 26 imposes no such elevated standard. FED. R. CIV. P. 26(b)(1).

matter of public importance," the first factor militates in favor of discovery. *In re Outpatient Med. Ctr. Emp. Antitrust Litig.*, 2023 WL 4181198, at *10 (N.D. Ill. June 26, 2023).[20]

Amount in Controversy. So too does the second one. Each family that has sued Abbott has a child who has suffered serious and in some cases disabling injuries. Each family that has sued Abbott seeks to recover actual and exemplary damages through several theories of recovery. Under these circumstances, it is far from unreasonable to ask a multibillion-dollar conglomerate like Abbott to fully respond to discovery. *See Oxbow Carbon & Minerals LLC v. Union Pac. R.R. Co.*, 322 F.R.D. 1, 7-8 (D.D.C. 2017).

Access to Information. Compared to Abbott, Plaintiffs have almost no access to information. Abbott designed, manufactured, and marketed its infant formulas and has far more information than Plaintiffs. *See BlueAlly, LLC*, 2017 WL 876266, at *4. Quite simply, Plaintiffs have no way to obtain this information other than to have Abbott produce it.[21] *Id.* Because Abbott is "in possession of relevant, unique information" regarding its infant formulas, the third factor also shows that Plaintiffs' date range is proportional to the needs of this case. *Id.*

Resources. Plaintiffs are mothers and fathers of injured children. These families have limited resources. Abbott's resources are far more substantial; it is one of the world's largest drug and device companies. Just last year, Abbott reported full-year sales of $43.7 billion dollars.[22] It neither strains logic nor bends reason to argue that Abbott has far more resources than the families

[20] *See also Human Rights Def. Ctr. v. Jeffreys*, 2022 WL 4386666, at *3 (N.D. Ill. Sept. 22, 2022); *Kelly v. City of Patterson*, 2021 WL 2821175, at *2 (D.N.J. July 7, 2021); *In re Ctr. for Military Readiness*, 2019 WL 4733602, at *5 (E.D. Mich. Sept. 28, 2019).

[21] The PSC's extensive public record requests to date have largely proven unproductive given the invocation of an ongoing investigation privilege by the Department of Justice, the Federal Trade Commission, the Food and Drug Administration and the Securities and Exchange Commission. Abbott declined executing a waiver to permit the FDA's production of unredacted documents.

[22] *See* https://www.abbottinvestor.com/static-files/d502f92e-e4ec-49de-96ce-3a96c2513f54 (last visited Aug. 22, 2023).

who have sought relief. This factor also weighs in favor of proportionality. *Union Pac. R.R. Co.*, 322 F.R.D. at 7-8.

Importance of Discovery. The discovery requests and time period to which Abbott objects concern the central issue in this case: safety conditions at Abbott's facilities and whether these conditions led to contamination that injured infants. *See BlueAlly, LLC*, 2017 WL 876266, at *5. This factor also supports proportionality. *Id*.

Burden Versus Benefit. The alleged burden imposed on Abbott is insubstantial because Plaintiffs chose a sensible, narrow time period and focused on certain injuries stemming from consumption of Abbott's products. Further, Abbott concedes it has already collected documents back through 2018. The benefit to Plaintiffs, in turn, is overwhelming because these documents will show what Abbott knew about the risk of contamination and when Abbott knew of that risk. This factor weighs in favor of Plaintiffs' discovery requests. *See id*.

Overall. Because Plaintiffs' date range is squarely proportional to the needs of this case, this Court should disregard Abbott's objections.[23]

2. <u>This Court Should Order Abbott to Produce Relevant Documents Abbott Previously Produced in the Preterm Infant Nutrition MDL.</u>

In another MDL involving injuries to children that is pending in this District, Abbott voluntarily produced many documents that mention not just PIF produced at Abbott's Sturgis facility, but also *Cronobacter* in the context of PIF production. Abbott already reviewed these documents to determine if they contained any privileged information or work product. Now,

[23] *See O2Cool, LLC*, 2023 WL 4556759, at *5; *cf. Hahn*, 2023 WL 2138926, at *3 ("There is no reason to believe that asking for 'all' documents relating to Plaintiff and her case would result in the production of anything other than documents relating to the facts at issue in this case . . . .").

though, Abbott has changed course, refusing to hand over any of these previously-produced documents. Absent from Abbott's refusal is any valid justification for it.

Both Johnson Becker and Aylstock, Witkin, Kreis and Overholtz represent plaintiffs in the Preterm Infant Nutrition MDL pending before Chief Judge Pallmeyer (MDL 3026)[24] and consolidated state court litigation, respectively. Both law firms have taken depositions and reviewed a significant amount of Abbott's internal documents within the context of the preterm formula litigation. The documents Abbott willingly produced are subject to a protective order that precludes dissemination to other counsel in this case that are not involved in that one.[25] Early in this MDL, the PSC raised the issue with Abbott's counsel. Abbott also has different counsel within the MDLs, so Plaintiffs sought a solution to the administrative issue facing the Parties – access to documents in one MDL that are not available in the other. The PSC proposed a simple solution. The PSC asked Abbott if it would run the agreed search terms in this case against documents produced in the Preterm Infant Nutrition MDL to identify and produce responsive documents in this MDL that were previously produced in that litigation.

Abbott refused. What's more, Abbott claims Plaintiffs seek "a large volume of documents from a separate MDL raising substantively distinct claims."[26] Although each case involves different infant formula products and different liability theories, Abbott decided to produce documents in that Preterm Formula Litigation that involve the same facility, products, and contaminants at the center of this case. And there is a common litigant in each case: Abbott. Plaintiffs are aware of the contents of the documents through their review in the preterm cases.

[24] *See* https://www.ilnd.uscourts.gov/mdl-details.aspx?Lbz1nwUsE4JWF/IQJN6GpA== (last visited Aug. 22, 2023).
[25] That protective order limits what Plaintiffs can discuss on the record or in open court. Plaintiffs, however, represent that they routinely came across these potentially crucial documents.
[26] *See* Joint Status Report for August 11, 2023 Case Management Conference (Dkt. 169) at p. 13.

However, Abbott's refusal places Plaintiffs in an untenable position: Plaintiffs cannot unknow the information derived from those documents but cannot violate the existing protective order and are prohibited from sharing with both other Plaintiff counsel and counsel for Abbott. Documents that reference infant formulas produced at Abbott's Sturgis facility as well as contamination of those products directly pertain to the strict liability and negligence claims here, in which Plaintiffs generally allege that Abbott failed to implement adequate safety practices.

Ultimately, Abbott produced documents in another case that plainly concerns this one and includes similar issues. The NEC plaintiffs did not demand that Abbott provide these documents; Abbott made that decision on its own. This document request is not a "fishing expedition" since Plaintiffs have seen relevant documents Abbott chose to produce in the other case. Abbott's refusal to produce the documents in this case is dubious. Since these documents are relevant and proportional to the needs of this case, Plaintiffs ask this Court to order Abbott to run the agreed search terms in this case against the documents it produced in the Preterm Infant Nutrition MDL.

3. This Court Should Order Abbott to Produce Documents Regarding Casa Grande.

There evidently is one other facility in the United States at which Abbott manufactures PIF: Casa Grande. Plaintiffs limited their discovery requests and sought documents regarding safety standards and practices at this facility. Abbott has agreed to produce documents that reference other facilities if those documents also reference Sturgis in a way that is responsive to Plaintiffs' discovery requests and consistent with Abbott's discovery responses. Still, this vague, open-ended proposal is insufficient.

Documents about safety practices and standards at another facility where Abbott makes PIF are relevant because they show whether, and to what extent, Abbott imposed different or more comprehensive safety practices at that facility. Further, documents regarding safety practices and

standards at Casa Grande will show whether Abbott took measures and precautions at Casa Grande that it could have taken, but failed to take, at Sturgis. These documents could also rebut any assertion by Abbott that what happened at the Sturgis facility was the result of a few isolated actors or "bad apples." These documents provide crucial context regarding Abbott's safety practices at the only other facility in the United States where Abbott manufactures infant formulas. Consequently, because these documents are relevant and proportional to the needs of this case, the PSC asks that this Court order Abbott to produce responsive documents regarding Casa Grande.

CONCLUSION

This Court should overrule Abbott's unfounded objections so discovery can begin in earnest.

Dated: August 22, 2023

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CERTIFICATE OF SERVICE

I certify that on August 22, 2023, a copy of the foregoing document was served electronically through the Court's electronic filing system upon all parties appearing on the Court's ECF service list.

DATED: August 22, 2023

/s/ Stacy K. Hauer
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